JUL 14 2003

510(k) Summary

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:**

Submitter's Name:	bioMérieux, Inc.
Submitter's Address:	100 Rodolphe Street, Durham, North Carolina 27712
Submitter's Telephone:	(919)-620-2968
Submitter's Contact:	Jocelyn Jennings, RAC
Date 510(k) Summary prepared:	May 29, 2003

(a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name:	**BacT/ALERT MP Culture Bottle**
Common or Usual Name:	**BacT/ALERT MP Culture Bottle**
Classification Name:	**Microbial Growth Monitor**

(a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: **BacT/ALERT MP Glass Process Bottle**

(a)(4) **A description of the device**

Device Description: The BacT/ALERT MP culture bottle was developed for the same intended use as the current BacT/ALERT MP Process Bottle (glass), when used in conjunction with the MB/BacT Reconstitution Fluid (for use with sterile specimens) or with MB BacT Antibiotic Supplement (for use with digested-decontaminated clinical specimens) is a selective growth medium for the *in vitro* culture recovery of mycobacteria organisms commonly encountered in body fluids other than blood and from digested-decontaminated clinical specimens. An inoculated bottle is placed into the MB BacT Detection instrument or the BacT/ALERT 3D instrument where it is incubated and continuously monitored for the presence of mycobacteria that will grow in the BacT/ALERT MP bottle.

(a)(5) A statement of the intended use of the device

Device Intended Use: The BacT/ALERT MP culture bottle is designed for use with the MB/BacT and the BacT/ALERT 3D Mycobacteria Detection Systems, for recovery and detection of mycobacteria from sterile body specimens other than blood, and from digested-decontaminated clinical specimens.

(a)(6) A summary of the technological characteristics of the new device in comparison to those of the predicate device

The BacT/ALERT MP Plastic Culture Bottle utilizes the same detection technology as the BacT/ALERT MP Glass Process Bottle. The similarities and/or differences with marketed device are listed in Table (a)(6) 1.

FEATURES	BACT/ALERT MP PLASTIC CULTURE BOTTLE	BACT/ALERT MP GLASS PROCESS BOTTLE (K993576)
Intended Use	Same	Same
Culture Bottle Material	Plastic	Glass
Product Code	MDB	MDB
Technology	Reflectance	Reflectance
Color change based on CO_2 production	Yes	Yes
Sensor	Emulsion	Emulsion
Indicator Material	Xylenol Blue in Silicone Emulsion	Xylenol Blue in Silicone Emulsion
Growth of microorganisms	Same	Same
Instrument Used	MB/BacT Mycobacterial Detection System and BacT/ALERT 3D Systems	MB/BacT Mycobacterial Detection System and BacT/ALERT 3D Systems
Sample source	Body fluids and digested-decontaminated clinical specimens	Body fluids and digested-decontaminated clinical specimens
Target Population	Adult	Adult

(b)(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency

Testing was performed to establish the performance characteristics of the new device including:

Seeded studies were performed on 12 organisms and inoculated into the BacT/ALERT MP Plastic Culture Bottle and the BacT/ALERT MP Glass Process Bottle.

(b)(2) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3)

The BacT/ALERT MP Plastic Culture Bottle was substantially equivalent to the BacT/ALERT MP Glass Process Bottle based on recovery of the 12 mycobacterial organisms included in the study. Detection times were substantially equivalent in both bottles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 14 2003

Jocelyn Jennings, RAC
Senior Regulatory Affairs Specialist
Biomerieux, Inc.
100 Rodolphe Street
Durham, NC 27712

Re: k031737
Trade/Device Name: BacT/ALERT MP Culture Bottle
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I
Product Code: MDB
Dated: June 3, 2003
Received: June 9, 2003

Dear Ms. Jennings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 031737

Device Name: BacT/ALERT MP Culture Bottle

Indications For Use:

The BacT/ALERT MP culture bottle is designed for use with the MB/BacT and the BacT/ALERT 3D Mycobacteria Detection Systems, for recovery and detection of mycobacteria from sterile body specimens other than blood, and from digested-decontaminated clinical specimens.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031737